

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

**IN RE: FRESENIUS
GRANUFLO/NATURALYTE
DIALYSATE PRODUCTS LIABILITY
LITIGATION**

MDL NO.: 1:13-MD-2428-DPW

This Document Relates to:

Mervin Boyd, Individually and as Wrongful Death Beneficiary of Judith Boyd,
Cause No. 1:13-cv-11717

**FILED UNDER SEAL
LEAVE TO FILE GRANTED ON 10/12/17**

Daniel Carter, Individually and as Wrongful Death Beneficiary of Anniece Carter,
Cause No. 1:13-cv-12459

Joyce Marie Clark, Individually and as Wrongful Death Beneficiary of Edward Lee Jenkins,
Cause No. 1:13-cv-12460

Gloria Cothern Dunaway, Individually and as Wrongful Death Beneficiary of Betty Sue Cothern,
Cause No. 1:13-cv-11714

Janice McGhee, Individually and as Wrongful Death Beneficiary of Henry McGhee,
Cause No. 1:13-cv-13172

Michael McNulty, Individually and as Wrongful Death Beneficiary of Willie Enette McNulty,
Cause No. 1:13-cv-12403

Kimberly Ross, Individually and as Wrongful Death Beneficiary of Stella Ross,
Cause No. 1:13-cv-12478

Beulah Williams, Individually and as Wrongful Death Beneficiary of Angela Hughes,
Cause No. 1:13-cv-12486

REDACTED

**RESPONSE IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT ON THE
CLAIMS OF OPT-OUT CASES LACKING EVIDENCE OF ELEVATED SERUM
BICARBONATE LEVELS**

**FILED UNDER SEAL
LEAVE TO FILE ENTERED 10/12/17**

NOW INTO COURT, through undersigned counsel, come the above-referenced Plaintiffs, who file their Response in Opposition to Motion for Summary Judgment on the Claims of Opt-Out Cases Lacking Evidence of Elevated Serum Bicarbonate Levels, and would show unto the Court the following:

The Fresenius Defendants are asking this Court to act as both Judge and Jury, and the Court should decline to do so. There are genuine issues of material fact regarding Pre-Dialysis Serum Bicarb levels in Plaintiffs' Decedents, and questions of fact are properly the province of a jury. The motion for summary judgment should be denied.

STANDARD FOR SUMMARY JUDGMENT

The standard for summary judgment is well-known. Summary judgment is appropriate only if there are no genuine issues of material fact and movant is entitled to judgment as a matter of law. Fed. R. Civ. Pro. 56. *Cross v. Cummins Engine Co.*, 993 F.2d 112 (5th Cir. 1993). Disputes over facts that might legitimately affect the outcome are material and, in applying the test, the court must view the evidence in the light most favorable to the nonmovant. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986).

BURDEN OF PROOF

At this stage in the litigation, absent case-specific discovery, Plaintiffs must proffer evidence that the product at issue is **capable** of causing their alleged injuries to prove general causation. *In Re Norplant Contraceptive Prods. Liab. Litig.*, 215 F.Supp. 2d 795, 830 (E.D. Tex. 2002)(emphasis added); *In Re Mirena IUD Prods. Liab. Litig.*, 202 F.Supp. 3d 304, 310 (S.D.N.Y. 2016). Generally, Plaintiff must then also proffer evidence that the product did, in fact, cause the injury in each individual case - i.e., specific causation. *Id.*

ARGUMENT

A. General Causation Cannot Be Credibly Contested

There are specific issues raised by Defendants in this pending motion regarding whether certain conclusions reached in the Hakim Memo should serve as the basis for summary judgment. Those issues will be discussed infra.

The Fresenius Defendants, however, cannot credibly contest general causation in this litigation. Attached hereto as Exhibit 1 is Plaintiffs' Omnibus Memorandum in Support of General Causation, which is incorporated by reference as if fully stated herein. Also attached as Exhibit 2 is the Memorandum of Decision and Order on the Plaintiffs' and Fresenius' Motions Pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.* and *Commonwealth v. Lanigan*, which was adopted by this Honorable Court in response to challenges to certain general causation and specific causation experts.

B. The Fundamental Flaw in Defendants' Argument in Support of Summary Judgment: The Hakim Memo Is Not the Basis for Plaintiffs' Theory of General Causation

During the course of this litigation, the Fresenius Defendants successfully sought to have the Hakim Memo excluded as evidence of general causation. Fresenius argued that the Memo was unreliable, unsupported, and speculative. Now they are asking this Court to accept that the Hakim Memo should serve to justify summary judgment in their favor. During the course of the *Ogburn* litigation¹, as Defendants are undoubtedly aware, the Plaintiff specifically agreed that she

¹*Ogburn* was a bellweather trial in Commonwealth of Massachusetts Superior Court, Civil Action No. 2013-05050.

would not use the Hakim memo as evidence of causation.² In *Ogburn*, the Plaintiff asked the Court to allow admission of the Memo only as to the issue of notice and as a non-hearsay party-admission.³

The Plaintiffs' actual theory of general causation is that excessive bicarbonate "total buffer"⁴ (defined as the sum of bicarbonate a patient may be exposed to during dialysis) in the "dialysate" (specifically Fresenius' GranuFlo and NaturaLyte), is capable of causing metabolic alkalosis, arrhythmia, sudden cardiac arrest (SCA), and death. The Plaintiffs allege that Fresenius should have warned physicians and other providers to be aware of total buffer when prescribing bicarbonate concentrate so as to avoid exposing a dialysis patient to a greater amount of serum bicarbonate than the patient's physician anticipated when prescribing the bicarbonate concentrate.

Plaintiffs, by and through discovery conducted thus far in this MDL, have proffered medical experts in nephrology, cardiology, epidemiology, biostatistics, and fluid dynamics to address the general causation question. These experts have opined that excessive bicarbonate total buffer in dialysates, including GranuFlo and NaturaLyte, causes a series of severe adverse health outcomes, including metabolic alkalosis, arrhythmia, sudden cardiac arrest (SCA), and death.⁵ Plaintiffs' experts provide detailed, well-reasoned, well-supported generally acceptable

²See Plaintiff's Motion to Admit the November 4, 2011 Memorandum Into Evidence At Trial, attached hereto as Exhibit 3. ("If the Court so rules, Plaintiff will not use statements made in the Memo to prove causation.")

³ The Omnibus Memorandum of Decision and Order on Major Motions in Limine is attached hereto as Exhibit 4.

⁴Fresenius has used the term "total buffer" in countless documents.

⁵See Exhibit 1.

mainstream text book opinions based on accepted and reliable methodologies.

Additionally, the remaining opt-out Plaintiffs have provided Lone Pine expert reports which conclude, to a reasonable degree of medical certainty, that GranuFlo and NaturaLyte did in fact cause alkalosis, arrhythmia, sudden cardiac arrest, and death in these particular cases. All of the aforementioned create genuine issues of material fact which preclude summary judgment.⁶

C. The Defendants Themselves Present the Court With Disputed Material Facts Which Preclude Summary Judgement

As has been previously determined, the Hakim Memo is relevant and admissible only as to whether Fresenius had actual notice of a problem with GranuFlo and NaturaLyte, and as an admission of a party opponent. **As Fresenius has previously argued, the “buckets” identified in the Hakim Memo are irrelevant as to general causation and this Court should not grant summary judgment on that basis⁷.**

Plaintiffs have proffered evidence that each of the Decedents at issue in this motion fall into at least one category which Plaintiffs’ experts have testified would “raise concerns”. The determination of whether each Decedent’s treating physician would have adjusted the bicarbonate setting in the circumstances would require case-specific discovery since Drs. Fine, Waikar, Goldfarb, Borkan and Aroesty were not involved in the treatment of these Decedents.

⁶See Expert Reports of Lucius Lampton, M.D., filed of record in each individual cause number, attached collectively as Exhibit 5.

⁷“Dr. Hakim reviewed data pertaining to 941 patients who experienced cardiopulmonary arrest during dialysis at FMCNA clinics, divided patients into different buckets based on their last reported pre-dialysis lab values, and attempted to identify their risk for experiencing such an event.” FMCNA’s Memorandum at p. 4.

1. Dr. David Goldfarb, Professor at New York University

Dr. Goldfarb testified that bicarbonate levels of [REDACTED]

[REDACTED] He further testified that he is “concerned about the individuals at the extremes.”

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 19, thereby placing her in the class of patients about which Dr. Goldfarb would be “concerned”.

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 19, thereby placing him in the class of patients about which Dr. Goldfarb would be “concerned”.

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 20, thereby placing him in the class of patients about which Dr. Goldfarb would be “concerned”.

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 19, thereby placing her in the class of patients about which Dr. Goldfarb would be “concerned”.

These Pre-Dialysis Serum Bicarb levels in each of the aforementioned Decedents, which fall into a category that Plaintiffs’ experts have identified as “of concern” create genuine issues of material fact which preclude summary judgment.⁸

2. Dr. Derek Fine, Associate Professor of Medicine at Johns Hopkins University School of Medicine

Dr. Fine testified that he [REDACTED]

[REDACTED]⁹

⁸The question of whether Dr. Goldfarb or Decedents’ treating physicians would testify that excessive bicarbonate buffer caused the injury/death of each particular decedent subject to this motion (specific causation) would require case-specific discovery.

⁹Defendants’ SOF ¶¶ 9, 11.

Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 25, thereby placing her in the class of patients about which Dr. Fine would be concerned.

Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 25, thereby placing her in the class of patients about which Dr. Fine would be concerned.

Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 26, thereby placing her in the class of patients about which Dr. Fine would be concerned. Decedent ██████████ died on May 17, 2017 while being dialyzed at a Fresenius Dialysis Clinic. Her cause of death was cardiac arrest.

These Pre-Dialysis Serum Bicarb levels create genuine issues of material fact which preclude summary judgment.¹⁰

3. Dr. Sushrut Waikar, Associate Professor of Medicine at Harvard Medical School¹¹

Dr. Waikar testified that the presence of chronic obstructive pulmonary disease (COPD) or the presence of severe metabolic alkalosis or acidosis would lead him to adjust the bicarbonate prescription for a patient.¹² Dr. Waikar further testified that his targeted range is “22 to 26, around there would be reasonable, maybe 22 to 24.”¹³

The Cause of Death for ██████████ is listed on her Death Certificate as Sudden

¹⁰The question of whether Dr. Fine or Decedents’ treating physicians would testify that excessive bicarbonate buffer caused the injury/death of each particular decedent subject to this motion (specific causation) would require case-specific discovery.

¹¹Dr. Waikar was proffered by the Plaintiffs to provide opinions on general causation in Plaintiffs (MDL) Omnibus Memo in Support of General Causation, which is attached as Exhibit 1 and is incorporated by reference as if fully re-stated herein.

¹²Defendants’ SOF ¶ 19.

¹³Defendants’ SOF ¶ 18.

Cardiac Death as a Consequence of COPD¹⁴, which potentially would have led Dr. Waikar to adjust her bicarbonate prescription.

Case-specific discovery would determine whether ██████████ suffered from chronic obstructive pulmonary disease (COPD), or any other consequential condition, which would lead Dr. Waikar or ██████████ treating physician to adjust her bicarbonate prescription.

Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 19, thereby placing her in the class of patients about which Dr. Waikar would be concerned.

Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 19, thereby placing him in the class of patients about which Dr. Waikar would be concerned.

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Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 19, thereby placing her in the class of patients about which Dr. Waikar would be concerned.

These Pre-Dialysis Serum Bicarb levels, plus information regarding COPD or other chronic pulmonary conditions, create genuine issues of material fact which preclude summary judgment.¹⁵

4. Dr. Steven Borkan, Professor at Boston University

Dr. Borkan testified that he does not “dial back the bicarbonate delivered in his prescription” to his patients unless the patient “has predialysis bicarbonate level that’s above

¹⁴Death Certificate is attached hereto as Exhibit 7.

¹⁵The question of whether Dr. Waikar or Decedents’ treating physicians would testify that excessive bicarbonate buffer caused the injury/death of each particular decedent subject to this motion (specific causation) would require case-specific discovery.

24.”¹⁶ In other words, he would “dial back” with a predialysis level of 25 or higher.

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 25, thereby placing her in the class of patients for which Dr. Borkan would “dial back” the bicarbonate level delivered.

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 25, thereby placing her in the class of patients for which Dr. Borkan would “dial back” the bicarbonate level delivered.

Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 26, thereby placing her in the class of patients for which Dr. Borkan would “dial back” the bicarbonate level delivered.

These Pre-Dialysis Serum Bicarb levels, consistent with levels at which Dr. Borkan testified he would alter the bicarb level, create genuine issues of fact which preclude summary judgment.¹⁷

By Defendants own admission, pursuant to the graph contained in their brief and the lab reports attached as exhibits, there are genuine issues of material fact as to each and every one of the aforementioned decedents which preclude summary judgment.

5. Dr. Julian Aroesty

Dr. Julian M. Aroesty, a cardiologist designated as an expert in the case, opines that the

[REDACTED]

[REDACTED]

[REDACTED]

¹⁶See Defendant SOF ¶ 26.

¹⁷The question of whether Dr. Borkan or Decedents’ treating physicians would testify that excessive bicarbonate buffer caused the injury/death of each particular decedent subject to this motion (specific causation) would require case-specific discovery.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
¹⁸ Dr. Aroesty further opined that “[REDACTED]”

[REDACTED]
[REDACTED]
[REDACTED].” The “epidemiology evidence (9:41, 9:18) provides evidence that [REDACTED]

[REDACTED].”(emphasis added).

Considering the aforementioned testimony regarding “target” serum bicarb levels, Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 19, providing evidence of the risk associated with low pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death.

Considering the aforementioned testimony regarding “target” serum bicarb levels, Decedent [REDACTED] had a last Pre-Dialysis Serum Bicarb level of 19, thereby providing evidence of the risk associated with low pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death.

Considering the aforementioned testimony regarding “target” serum bicarb levels,

¹⁸Exhibit 6: Aroesty Report at 18.

Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 19, providing evidence of the risk associated with low pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death.

Considering the aforementioned testimony regarding “target” serum bicarb levels, Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 19, providing evidence of the risk associated with low pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death.

Considering the aforementioned testimony regarding “target” serum bicarb levels, Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 25, providing evidence of the risk associated with high pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death. .

Considering the aforementioned testimony regarding “target” serum bicarb levels, Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 25, providing evidence of the risk associated with high pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death.

Considering the aforementioned testimony regarding “target” serum bicarb levels, Decedent ██████████ had a last Pre-Dialysis Serum Bicarb level of 26, providing evidence of the risk associated with high pre-dialysis serum bicarbonate values for sudden cardiac arrest and sudden cardiac death.

“Target” serum bicarbonate values are a question of fact, for a finder of fact, after hearing testimony from the experts in the case and from each Decedent’s treating physician. Proffered reports and testimony from experts Drs. Goldfarb, Fine, Waikar, Borkan and Aroesty provide general causation evidence as to each element of Plaintiffs’ claims. The Court should deny the

motion for summary judgment.

D. Dr. Steven C. Borkan's Opinions Have Survived *Daubert* Scrutiny in Both State and Federal Court and Establish General Causation

Dr. Steven Borkan is a nephrologist the Plaintiffs named as an expert in general causation. Dr. Borkan has expressed the following opinions, in his expert report, at deposition, and at trial:

- In his report, Dr. Borkan opined that Fresenius [REDACTED] [REDACTED] [REDACTED].” Fresenius sought to preclude Dr. Borkan from expressing this opinion but the motion to preclude was DENIED¹⁹.
- Dr. Borkan testified that he is [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].” Dr. Borkan Deposition at 51-53.
- Throughout his expert report, Dr. Borkan references various journal articles as support for his [REDACTED].” Dr. Borkan Report at 22.
- This Court has previously ruled that Dr. Borkan may testify that the greater amount of acetate, the great the potential impact on a patient’s serum bicarbonate.
- In his report, Dr. Borkan opined that [REDACTED]
[REDACTED]
[REDACTED].”
Dr. Borkan Report at 29.
- Dr. Borkan, referenced the “Graham Study” from 2001, involving “[REDACTED]

¹⁹The Order On the Plaintiffs’ and Fresenius’ Motions Pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, and *Commonwealth v. Lanigan*, Doc. 1568-1, filed 12/04/15, is incorporated by reference.

■.” Fresenius sought to preclude Dr. Borkan from expressing these opinions, but the motion was DENIED.

In his report and his deposition testimony, Dr. Borkan provides expert testimony regarding each element of Plaintiffs' claim and, taking the evidence in the light most favorable to the nonmovant, summary judgment must be denied.

CONCLUSION AS TO GENERAL CAUSATION

By and through the motion currently pending before this Court, Fresenius is attempting a “second bite” at the general causation apple. Plaintiffs’ theory of general causation is that as a result of the conversion of acetate into bicarbonate, the patient’s serum bicarbonate levels increase, thereby exposing the dialysis patient to a greater amount of serum bicarbonate than the patient’s physician anticipated when prescribing the bicarbonate concentrate. Over time, then, the patient develops higher levels of serum bicarbonate, which, in turn, increases the risk of arrhythmia, cardiopulmonary arrest, and sudden cardiac arrest. Plaintiffs have proffered evidence as to each element of their claims.

For all of the aforementioned reasons, general causation in this case cannot be credibly contested. The totality and the weight of the evidence, particularly when viewing the evidence in the light most favorable to the non-movant, support causation. The question of causation is a material issue of fact for a jury, and the motion for summary judgment must be denied.

E. In the Alternative, Plaintiffs Request Additional Time Pursuant to Rule 56(d)

In the alternative, Plaintiffs request additional time to respond to the Motion for Summary

Judgment On Claims of Opt-Out Cases Lacking Evidence of Elevated Serum Bicarbonate Levels
in order to conduct case-specific discovery as to each Decedent named herein.²⁰

CONCLUSION

Repeatedly throughout the course of this litigation, the Fresenius Defendants stood before this Court and argued that the Hakim Memo was unreliable, unsupported, and speculative. Now, in the context of opt-out Plaintiffs whose counsel was not involved in the litigation up until this point, they are asking this Court to grant summary judgment based on that same unreliable, unsupported, and speculative document. This Court should decline to grant that relief. The motion for summary judgment should be denied.

This the 16th day of October, 2017.

Respectfully submitted,

s/Dunbar Watt
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²⁰In accordance with Rule 56(d), the affidavit of Dunbar Watt is attached as Exhibit 8.

CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of October, 2017, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send notice of electronic filing to all counsel of record. I further certify that I mailed the foregoing document and the notice of electronic filing by first-class mail to those who are non-CM/ECF participants.

s/Dunbar Watt
Dunbar Watt, Esq.
Attorney for Plaintiffs